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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/230,955	05/04/1999	ROBERT JAMES MASON	A-67653/DCA/	3606

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EXAMINER	
BRUMBACK, BRENDA G	
ART UNIT	**PAPER NUMBER**
1642	18

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/230,955	Applicant(s) MASON ET AL.	
	Examiner Brenda G. Brumback	Art Unit 1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 April 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☒ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See attached.*.

3. ☒ Applicant's reply has overcome the following rejection(s): *See Continuation Sheet*.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See attached.*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *5 and 7*.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-4 and 8*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 3. Applicant's reply has overcome the following rejection(s): the rejection of claims 1, 2, and 4 under 35 U.S.C. 112, second paragraph.

DETAILED ACTION

Attachment to Advisory Action

Item # 2:

Applicant's proposed amendment of claim 1 raises the issue of new matter. While applicant's comments regarding the alleged support for the amendment at pages 4 and 17 are noted, support was not found for the proposed amendment as indicated. Applicant is invited to further clarify how the referenced portions provide support for the proposed amendment of claim 1 or to point to other support in the specification as a possible means of resolving the issue.

It is noted that support for the proposed amendments to claims 4 and 8 was found as indicated at page 12.

Item # 5:

The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as anticipated by Porta et al. is maintained. Applicant's arguments with the English translation of Porta et al. and the accompanying Jha et al. and Epenetos et al. references have been considered but they are not persuasive for the following reasons.

Applicant argues that Porta et al. do not anticipate the present claims, but rather teach away by teaching that Epenetos et al. use monoclonal antibodies for diagnosis of other than cervical neoplasia and that Jha et al. teach that monoclonal antibodies did not differentiate normal and neoplastic tissue. However, Porta et al. teach that monoclonal antibodies have been successfully used by others to screen for neoplasia of the cervix by staining cells in a cervical smear sample. While Porta et al. do teach that Jha et al. reported that one particular panel of monoclonal antibodies were not successful in differentiating neoplastic and normal cells, they also teach that other researchers have successfully used monoclonal

antibodies for differentiation of neoplastic and normal cells in cervical smear samples. Applicant is reminded that the claimed method is not drawn to the specific monoclonal antibody panel used by Jha, but rather is drawn to a method of differentiating neoplastic or premalignant cells from normal cells using a panel of two or more of any monoclonal antibodies. Applicant is reminded that absolute predictability is not required, but rather a reasonable expectation of success. Taken as a whole, the teachings of Porta et al. support such a reasonable expectation of success.

The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as anticipated by Smedts et al. is maintained. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that the monoclonal antibodies used by Smedts et al. were raised against synthetic antigens and thus Smedts et al. does not anticipate the claimed invention, which uses monoclonal antibodies raised against antigens present on normal cells. While Smedts et al. do teach that the panel of antibodies used were raised against synthetically made keratins, the keratins against which the monoclonal antibodies were raised are also present on normal cells. Even if the antigens used by Smedts et al. to raise the monoclonal antibodies were structurally different from the keratins present on normal cells, absent some evidence to the contrary, the antibodies used by Smedts et al. would be expected to have the same reactivity as monoclonal antibodies raised against keratins derived from natural sources. The panel of monoclonal antibodies used in the claimed method would thus be viewed as a product-by-process. Even though the products are defined by the claimed process, determination of patentability is based on the product itself. The claimed products and methods are not patentable over those of the prior art absent any distinct difference in the products or methods themselves (see MPEP § 2113).

The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as obvious over Smedts et al. is maintained. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that the method of Smedts et al. would not work for cervical smear samples because Smedts et al. teach staining cells which have kept their original structure; however, one of skill in the art at the time the invention was made would have expected monoclonal antibodies to react with the same cellular antigens regardless of whether the cells retained their original tissue structure or were smeared onto a slide. Applicant has provided no evidence to the contrary. Argument in the absence of evidence is not persuasive.

Applicant argues that for the method of Smedts et al. to be effective, the type of cell being tested must be known. The relevance of this argument, however, is not apparent, as the same would seem to be true of applicant's claimed method, which is drawn specifically to a smear of cervical cells.

The rejection of claim 8 under 35 U.S.C. 102(b) as anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over either of Porta et al. or Smedts et al. is also maintained.

Applicant argues that neither Porta et al. nor Smedts et al. teaches a specific binding substance able to bind to an antigen of cervical tissue to which a hybridoma selected from those deposited can bind. Applicant's claims are not drawn to monoclonals which bind the specific epitopes bound by the monoclonals of the deposited hybridomas, but rather are drawn any monoclonal that binds any part of any antigen that binds any of the monoclonals produced by any of the deposited hybridomas. Applicant has provided no evidence that the monoclonal antibodies used by Porta et al. or Smedts et al. bind a different antigen. Once again, argument in the absence of evidence is not persuasive.

The rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, is maintained. Applicant's arguments have been fully considered but they are not persuasive.

Applicant makes the general statement that it is clear from the specification as filed that the staining pattern is significantly different between premalignant and normal specimens; however, applicant has neither addressed any of the apparent discrepancies between the data and this conclusion which were brought forth in the previous Office action nor addressed the differences in the scope of the invention as claimed (two or more antibodies) and the data (a panel of five antibodies) presented in the specification.

If entered, applicant's amendment would overcome the rejection of claims 1, 2, and 4 under 35 U.S.C. 112, first paragraph, for new matter for the original reasons but would be newly rejected under 35 U.S.C. 112, first paragraph for the reasons outlined *supra* (Item # 2).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Official FAX telephone number is (703) 872-9306 and the After Final FAX telephone number is (703) 872-9307. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB

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